

Progen Pharmaceuticals Licensee submits updated Special Protocol Assessment to US FDA for Phase III clinical trials of PI-88

1st September 2010. The Directors of Progen Pharmaceuticals Limited (ASX:PGL, OTC:PGLA) provide the following update on muparfostat (PI-88).

Progen Licensee Medigen Biotechnology Corp has announced to the Taiwan Stock Exchange that on the 30th August 2010 it had submitted its requisition for a Special Protocol Assessment (SPA) package to the Food and Drug Administration (FDA) in the USA.

The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application (NDA). Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program.

Medigen has successfully completed the PI-88 phase II HCC trial in 6 medical centers in Taiwan in the past. The trial has shown promising effects on reduction of tumor recurrence in liver cancer patients who had had their tumors resected. In the SPA package submitted to the USFDA, Medigen intends to recruit 500 patients globally, and to use DFS (Disease Free Survival) as the primary efficacy end-point. Source of study patients are likely to be from China, Taiwan, Korea, Hong Kong, Singapore, USA, Canada and some nations of the EU.

If the SPA is granted there will be the potential to save significant cost and time for the PI-88 project.

Progen announced in June 2010 that it had signed a License and Collaboration Agreement with Medigen Biotech Corporation (Taipei, Taiwan) for the development and commercialisation of muparfostat (PI-88) for oncology indications globally.

“The progress announced by Medigen today shows that the muparfostat (PI-88) development program is firmly back on track and we wish the Medigen team every success with this application to the US FDA” said Sue MacLeman, Chief Executive Officer, Progen Pharmaceuticals Ltd.

Muparfostat is a multi-targeted cancer therapeutic in late stage development which inhibits both angiogenesis (or tumour promoting) factors such as Vascular Endothelial Growth Factor (VEGF), Fibroblast Growth Factors (FGF) 1 and 2, and heparanase, an enzyme implicated in metastasis (tumour spread).

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About Progen Pharmaceuticals Ltd

Progen Pharmaceuticals Limited is a biotechnology company committed to the discovery, development and commercialization of small molecule pharmaceuticals primarily for the treatment of cancer. Progen has built a focus and strength in anti-cancer drug discovery and development. Progen targets the multiple mechanisms of cancer across its three technology platforms of angiogenesis, epigenetics and cell proliferation. Progen has operations in Australia and the United States of America. www.progen-pharma.com

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This release contains forward-looking statements that are based on current management expectations. These statements may differ materially from actual future events or results due to certain risks and uncertainties, including without limitation, risks associated with drug development and manufacture, risks inherent in the extensive regulatory approval process mandated by, amongst others, the United States Food and Drug Administration and the Australian Therapeutic Goods Administration, delays in obtaining the necessary approvals for clinical testing, patient recruitment, delays in the conduct of clinical trials, market acceptance of PI-88, PG11047, PG545, PG562, PG11122, PG11144 and other drugs, future capital needs, general economic conditions, and other risks and uncertainties detailed from time to time in the Company's filings with the Australian Securities Exchange and the United States Securities and Exchange Commission. Moreover, there can be no assurance that others will not independently develop similar products or processes or design around patents owned or licensed by the Company, or that patents owned or licensed by the Company will provide meaningful protection or competitive advantages.